DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 8, 2014

Ivoclar Vivadent, Incorporated
Ms. Donna Hartnett
Director QA/Regulatory Affairs
175 Pineview Drive
Amherst, NY 14228

Re: K131487
Trade/Device Name: Fluor Protector S
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: September 3, 2014
Received: September 4, 2014

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131487

Device Name: Fluor Protector S

Indications For Use:

- Treatment of dentinal hypersensitivity
- Treatment of exposed cervicals
- Treatment of sensitivity after tooth whitening

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

Fluor Protector S
Revised October 7, 2014

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent. 175 Pineview Drive, Amherst, NY 14228
(716) 691-0010

Date Prepared:

Proprietary Name: Fluor Protector S

Classification Name: Cavity Varnish (872.3260)

Predicate Devices: Fluor Protector (K946032)

Device Description: Fluor Protector S is a desensitizing agent used for sealing of dentinal tubules for the treatment of hypersensitive teeth, sensitive root surfaces and for cavity preparation.

The predicate device to which Fluor Protector S has been compared is Fluor Protector (K946032). For this application, Fluor Protector S has been compared to its predicate with regard to chemical composition, performance data and indications for use. The primary difference between the subject device and the predicate device is the use of Ammonium fluoride in the subject de vice. Even though there is an approximately 8-fold difference in fluoride content in solution between the subject device and the predicate device, the difference is only 3.6-fold in the dry varnish, which is the "active state" of the device. Apart from fluoride content, the varnishes are very similar (low viscosity, clear, transparent, multi- and single dose). The comparison shows that Fluor Protector S is substantially equivalent to the predicate device.

Intended Use:
- Treatment of dentinal hypersensitivity
- Treatment of exposed cervicals
- Treatment of sensitivity after tooth whitening

Technological Characteristics: The device design, i.e. delivery form, and intended use of Fluor Protector S and the predicate device are the same. The composition of the subject device has been modified from the predicate, however, there are no ingredients in the subject device which pose any new issues of safety and effectiveness.

Testing Summary: The device was tested in accordance with ISO 1641:2009 Dentistry – Medical devices for dentistry – Materials. Biocompatibility testing and evaluation was also carried out according to ISO 10993 where the following tests were conducted on the subject device and the predicate device: Cytotoxicity, genotoxicity, sensitization, oral irritation, Acute systemic toxicity. All results show favorable biocompatibility for the subject device.

Conclusion: Fluor Protector S is substantially equivalent to the predicate device.